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11 UNITED STATES DISTRICT COURT
12 FOR THE EASTERN DISTRICT OF WASHINGTON
13

14 STATE OF WASHINGTON, *et al.*,

No. 1:23-cv-03026

15 Plaintiffs,

NOTICE OF SUPPLEMENTAL
INFORMATION

16 v.

17 U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

18
19 On March 28, 2023, this Court held oral argument on Plaintiff States'
20 Motion for Preliminary Injunction. ECF Dkt. 70. During the argument, the Court
21 asked counsel for Defendants whether any drugs other than Mifeprex
22 (mifepristone) are subject to a Risk Evaluation and Mitigation Strategy (REMS)
23 that includes a pharmacy certification requirement. *See* 21 U.S.C. § 355-1(f)(3)(B).
24
25 Upon further review of the REMS for approved drugs and biological products
26

1 posted on FDA’s website,¹ Defendants have determined that more than three dozen
2 other new drug application (NDA) or biologics license application (BLA) products
3
4 (not including abbreviated new drug application (ANDA) products, *i.e.*,
5 “generics”) are subject to a REMS that includes a pharmacy certification
6 requirement: Letairis (ambrisentan), Tracleer (bosentan), Camzyos (mavacamtem),
7
8 Caprelsa (vandetanib), Clozaril (clozapine), Fazaclo ODT (clozapine), Versacloz
9 (clozapine), Empaveli (pegcetacoplan), Filspari (sparsentan), Fintepla
10 (fenfluramine hydrochloride), Absorica (isotretinoin), Absorica LD (isotretinoin),
11
12 Juxtapid (lomitapide), Jynarque (tolvaptan), Lemtrada (alemtuzumab), Revlimid
13 (lenalidomide), Opsumit (macitentan), Myalept (metreleptin), Natpara
14 (parathyroid hormone), Palforzia (peanut (*Arachis hyogaea*) allergen powder-
15
16 dnfp), Palynziq (pegvaliase-pqpz), Pomalyst (pomalidomide), Probuphine
17 (buprenorphine hydrochloride), Qsymia (phentermine and topiramate), Adempas
18 (riociguat), Siliq (brodalumab), Spravato (esketamine), Sublocade (buprenorphine
19 extended-release), Tecvalyi (teclistamab-cqyv), Tegsedi (inotersen), Thalomid
20 (thalidomide), Actiq (fentanyl citrate), Fentora (fentanyl citrate), Lazanda (fentanyl
21 citrate), Onsolis (fentanyl citrate), Subsys (fentanyl), Turalio (pexdartinib), Tysabri
22 (natalizumab), Sabril (vigabatrin), Xiaflex (collagenase clostridium histolyticum)
23
24
25

26 ¹ <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>

1 (for the Peyronie's disease indication), Xyrem/Xywav (calcium, magnesium,
2 potassium, and sodium oxybates), Zulresso (brexanolone), and Zyprexa Relprevv
3 (olanzapine).
4

5 March 29, 2023

HILARY K. PERKINS
Assistant Director

7 /s/ Noah T. Katzen
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1 **CERTIFICATE OF SERVICE**

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3 I hereby certify that, on March 29, 2023, I electronically filed the foregoing

4 with the Clerk of the Court using the CM/ECF system, which will send notification

5 of such filing to all counsel of record.

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8 /s/ Noah T. Katzen

9 NOAH T. KATZEN

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